

# The stability of three different cementless tibial components

## A randomized radiostereometric study in 45 knee arthroplasty patients

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We conducted a prospective, randomized study of 45 patients to evaluate 3 different uncemented tibial component designs in total knee arthroplasty. The stability of the components was assessed by radiostereometry (RSA), both as migration during 2 years and as inducible displacement at 2 years. The PCA resurfacing, the Tricon stem and the Tricon-M prosthesis groups showed a similar level of migration at 2 years, about 1.4 mm. In response to externally applied rotatory forces, the Tricon groups rotated more than the PCA group, interpreted as a

consequence of the more conforming articular surface in the Tricon design.

The series was divided into one group of continuously migrating prostheses with a poor prognosis (unstable, one third) and another group of prostheses in which migration stopped after 1 year (stable, two thirds). With this classification, no differences between the prostheses design groups were revealed. However, the unstable group showed a larger inducible displacement by provocation, an association hitherto not established.

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The mechanisms of tibial component loosening are not fully understood. Whether cementless techniques introduced some 15 years ago improve fixation is debatable. Long-term (> 10 years) follow-up data are not available and conclusions are therefore difficult to arrive at. Furthermore the diversity of the patient groups makes comparisons complicated and uncertain.

Recently, the early migratory pattern of the tibial component has proved to be of prognostic value with regard to late component loosening (Ryd et al. 1993, 1995). Radiostereometric analyses have consistently revealed micromotions during the first year after operation (Ryd 1986, Albrektsson 1991, Nilsson 1992, Toksvig-Larsen 1992), whereafter the majority of the prostheses settle and do not move any further (Ryd et al. 1993, 1995). All cases of subsequent loosening have been found in the group of prostheses continuously migrating after 1 year (Ryd et al. 1993, 1995). A similar pattern has been reported for the femoral component in hip arthroplasty (Freeman and Plante-Bordeneuve 1994, Kärrholm et al. 1994).

We assessed the stability of 3 different cementless designs of tibial components by radiostereometry, regarding both the spontaneous migration during a 2-year period and displacement induced by externally applied forces at 2 years. Specifically, we

wished to assess the effects of a stem and the compatibility of the immediate-interlocking peg concept (Blaha et al. 1982) with long-term fixation.

### Patients and methods

During the period 1989-1992, 45 patients with gonarthrosis were treated with total knee arthroplasty at the Orthopedic Department, Central Hospital of Västerås, Sweden. The selection criteria were arthrosis stages III-V, according to Ahlbäck (1968), no previous knee prosthesis or osteotomy operation or fracture of the knee, no systemic illness affecting the skeleton and no steroid medication. The age limits were 60-75 years. Patients fulfilling the inclusion criteria were entered consecutively after giving informed consent. The study was approved by the Ethics Committee of Karolinska Institute, Stockholm.

To ensure an equal number of patients in each group and to compensate for possible time-dependent effects, randomization was achieved by closed envelopes, one from each group in triplets, the internal order of which was subjected to chance. The prostheses were: Tricon-M and Tricon stem (both from Smith & Nephew, Memphis, TN), and PCA

Table 1. Demographic, radiographic and clinical data, and classification of stability

| Group       | Sex            | Age  | Stage <sup>a</sup> | Weight | HKA <sup>b</sup> |         | PT <sup>c</sup> | PTS <sup>d</sup> | Score <sup>e</sup> | Stab <sup>f</sup> |
|-------------|----------------|------|--------------------|--------|------------------|---------|-----------------|------------------|--------------------|-------------------|
|             |                |      |                    |        | M/F              | kg      |                 |                  |                    |                   |
| PCA         | mean <i>SD</i> | 70 5 | 4                  | 81 14  | 170 12           | 177 3   | 88 1            | 85 2             | 90 4               |                   |
|             | ratio or range | 6/9  | 61-74              | 3-5    | 62-108           | 155-196 | 172-182         | 86-90            | 82-88              | 80-94             |
| Tricon stem | mean <i>SD</i> | 69 4 | 4                  | 79 9   | 171 10           | 179 4   | 89 2            | 89 4             | 85 7               |                   |
|             | ratio or range | 6/9  | 62-75              | 3-5    | 67-94            | 160-195 | 174-188         | 86-93            | 83-97              | 71-93             |
| Tricon-M    | mean <i>SD</i> | 70 3 | 4                  | 77 14  | 171 9            | 180 3   | 90 2            | 89 4             | 86 6               |                   |
|             | ratio or range | 5/10 | 65-74              | 3-5    | 57-112           | 158-192 | 174-185         | 87-94            | 82-94              | 71-94             |

<sup>a</sup> Arthrosis stage according to Ahlbäck's classification (1968)

<sup>b</sup> Hip-knee-ankle angle from frontal long-leg radiographs, pre preoperative, post 6 months postoperative

<sup>c</sup> Frontal prosthesis-tibia angle 6 months postoperative

<sup>d</sup> Lateral prosthesis-tibia (-side) angle 6 months postoperative

<sup>e</sup> Hospital for Special Surgery Score (Insall et al. 1976) at 2 years

<sup>f</sup> Stability classification yes/no, cutoff level 0.2 mm of MTPM the second year.

resurfacing (Howmedica, Rutherford, NJ). The femoral components of Tricon-M and Tricon stem were identical.

There were no differences between the 3 prosthesis groups preoperatively regarding age, arthrosis stage, weight, sex, alignment (HKA) or clinical score (HSS) (Table 1).

The operations were all done in a standardized manner by 2 experienced surgeons, who did not take part in the evaluation of the results. The posterior cruciate ligament was retained. Patella components were used in all cases. No acrylic bone cement was used.

At the operation, the proximal tibia and the plastic part of the tibial component were prepared for radio-stereometric analysis (RSA; Ryd 1986, Selvik 1989) by insertion of 0.8 mm tantalum balls, 6 (4-7) in the metaphyseal region and 4 in the plastic insert.

The first RSA was done during the first post-operative day, before any weight bearing or straight-leg raising exercises had started. Instructions included partial weight bearing during 6 weeks. Subsequent stereoradiograms were obtained on the tenth day, at 6 weeks, 6 months, 1 year and 2 years. Clinical and conventional radiographic data were then collected, as had been done before operation. Pain and function was graded according to the Hospital for Special Surgery Score (HSS) (Insall et al. 1976). Alignment was measured from frontal long-leg radiographs as the hip-knee-ankle (HKA) angle. Radiographic data from this study have been published previously (Hilding et al. 1993).

The first RSA examination served as reference; further angular and translational movements were related to the position of the knee at that time. Care was taken in positioning the knee according to the

principal axes in the cage. On examination, the patient was supine. In addition, at the 2-year control, a series of standing examinations with defined positions and external forces were applied. These so-called stress series were obtained to investigate inducible displacement. They included the following positions: 1) supine, 2) standing with weight on the operated leg, 3) standing with the operated leg on a mobile plate with an outwardly rotating torque of 10 Nm applied, which the patient should resist, 4) similar as 3) but an inwardly directed torque, and 5) standing with weight on the operated leg in 45-60° flexion.

All standing positions were compared to the supine position. Position 3 was also compared to position 4 (Ryd 1986, Ryd and Toksvig-Larsen 1993).

The mathematical evaluation of the radiographic examinations was performed by rigid-body kinematics, according to Selvik (1989). The stability of individual markers within each segment was assessed by minimization of the mean error of rigid body-fitting. Unacceptably high values of separate markers indicate instability and such markers were omitted from further calculations. The upper limit was set at 300 µm, mean value 105 (SD 58) and the highest value was 294, except at one provocation when a value of 350 was accepted. The condition number, a reflexion of how well the markers were spread apart, was obtained from the program KINERR (Unikum, Umeå), used in only 36 of the patients; the mean value was 40 (range 19-191). The reproducibility of the set-up was examined by 16 stereo exposures on a plastic tibial model with a mounted prosthesis and stable markers, with change of positions of the model and the x-ray tubes between the exposures. The standard deviations were 0.05°, 0.02°, 0.04° for

Table 2. Magnitude and direction of migration during 2 years in the 3 prosthesis groups. Mean, SD

|             | Segment motion at 2 years |      |      |                  |                |      |       |      |       |      |      |      |
|-------------|---------------------------|------|------|------------------|----------------|------|-------|------|-------|------|------|------|
|             | Rotation (°)              |      |      | Translation (mm) |                |      |       |      |       |      |      |      |
|             | X                         | Y    | Z    | X                | Y <sup>a</sup> | Z    |       |      |       |      |      |      |
| PCA         | -0.46                     | 0.95 | 0.66 | 1.22             | -0.02          | 0.97 | -0.08 | 0.35 | -0.42 | 0.58 | 0.18 | 0.45 |
| Tricon stem | -0.28                     | 0.66 | 0.51 | 1.14             | 0.23           | 0.62 | 0.04  | 0.16 | -0.77 | 0.36 | 0.12 | 0.25 |
| Tricon-M    | -0.19                     | 1.27 | 0.17 | 0.74             | 0.40           | 1.01 | 0.02  | 0.19 | -0.76 | 0.37 | 0.33 | 0.32 |

<sup>a</sup>  $P < 0.003$

X Transverse axis. Positive sign if translation is directed laterally and if rotation occurs as anterior tilting

Y Vertical axis. Positive sign if translation is directed cranially and if rotation occurs outwards

Z Sagittal axis. Positive sign if translation is directed anteriorly and if rotation occurs as varus tilting.

rotations, and 0.02 mm, 0.02 mm and 0.07 mm for translations.

Results were obtained as rotation and translation of the tibial component relative to the tibia, named segment motion (SM). The definition of the principal axes, x, y and z, and the direction of motions are explained in Table 2. The tibial component is represented by the geometric center of the rigid body and is thus dependent on the localization of the individual markers. These were inserted in a standardized pattern as a rectangle, 2 anteriorly and 2 posteriorly, near the edges. In most cases, all 4 markers were visible.

Results can also be expressed as movements of individual markers, point motion. The maximum total point motion (MTPM) refers to the marker that moves the most and represents the three-dimensional vector-sum of that motion, given without direction.

In the light of the recently established prognostic value of the migration level in the second postoperative year (Ryd et al. 1993, 1995), another classification was made. Regardless of type of prosthesis, the material was divided into one stable and one continuously migrating group (unstable). The criterion for stability was  $< 200 \mu\text{m}$  MTPM migration in the second year. The stability during that time in SM was also considered and in 77 percent it coincided with the MTPM stability criterion. All borderline cases were further analyzed and 2 cases with  $> 200 \mu\text{m}$  MTPM were judged as stable due to the absence of SM.

2 patients who belonged to the Tricon-M group died during the follow-up period. Their data are excluded. 1 patient in the Tricon stem group had an insufficient number of markers visible at the reference examination for measurement of SM, but MTPM could be determined, as well as both SM and MTPM from the stress series, and she is included. 1 man in the Tricon-M group was reoperated at 1 year

due to wear of the patella component. Synovectomy and patella component removal were performed. No sign of loosening of the components was found and he is doing well clinically, and still participating in the study. All patients attended all the scheduled controls.

The statistical methods used were the independent *t*-test for comparisons of 2 groups, and analysis of variance (ANOVA) for 3 groups, if the variables were normally distributed (estimated by Lilliefors test). If not, non-parametric analyses of variances were used (Mann-Whitney U-test for 2 groups, Kruskal-Wallis for more than 2 groups). Chi-square analysis was used to compare groups with categorical variables. *P*-values  $< 0.05$  were considered significant.

## Results

After 2 years, all patients had HSS scores indicating a good or excellent clinical result and complete radiolucent lines  $> 2$  mm beneath the tibial components were not seen in any case.

The migratory patterns measured as MTPM during 2 years were similar in the PCA, Tricon stem and Tricon-M groups (Figure 1). The largest part of the migration occurred up to 6 months, whereafter the curve leveled off. The mean value at 2 years was 1.5 mm in the Tricon-M group, 1.4 mm in the PCA group and 1.3 mm in the Tricon stem group.

Migration, expressed as SM around and along the 3 cardinal axes, showed considerable variations between individual cases. The largest migration was seen distally along the y-axis, subsidence, and it was larger in both Tricon groups than in the PCA group (Table 2,  $P < 0.003$ ). Along the x- and z-axes hardly any translations occurred. Some outward rotations around the y-axis were recorded, but no differences

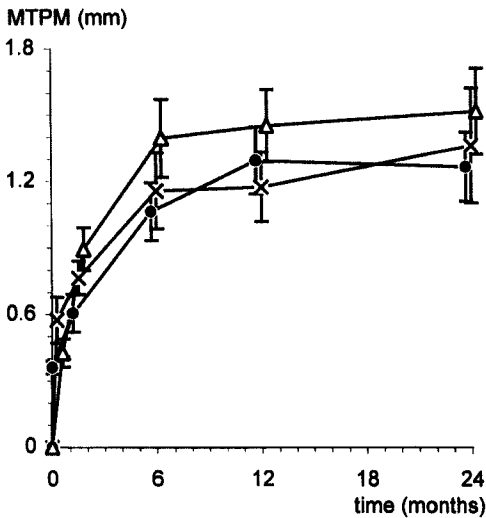


Figure 1. Migration (MTPM magnitude but not direction) during 2 years of the tibial components in the 3 prosthesis groups, x PCA (n 15), ● Tricon stem (n 15), Δ Tricon-M (n 13) (mean ± SEM).

between groups. Rotations around the x- and z-axes were all below  $0.5^\circ$  on the average, but the standard deviation was high (Table 2).

Inducible displacement, measured as  $SM > 0.3^\circ$  or  $> 0.2$  mm in the individual case, occurred in all patients, except three—one from each group. Also here, the magnitude and direction of motions varied, and the only significant difference between groups was in rotation (Table 3). When an outwardly directed rotatory force was applied to the foot, the Tricon prostheses rotated inwards, significantly more than the almost immobile PCA group ( $P 0.023$ ). When the positions from rotatory forces in both directions were compared, the total rotatory

movements in the Tricon groups were significantly larger than in the PCA group ( $P 0.027$ ). The squatting position (5) was technically difficult to obtain and only 17 cases could be analyzed. A tendency of posterior tilt was observed in all groups. The Tricon groups also showed a slight valgus tilt and some outward rotation occurred in the Tricon stem group. MTPM was not different between groups in standing positions with rotatory forces applied or in flexion. Only in position 2 the PCA prostheses showed less displacement ( $P 0.02$ ).

Classification of all patients by the stability criteria indicated that 28 knees were stable and 15 were unstable. No significant differences in the distribution between the prosthetic groups were found (Table 1). The stability criteria correlated well with the total level of migration. Mean MTPM at 2 years was 1.1 mm (SD 0.5) in the stable group and 1.9 mm (SD 0.9) in the unstable group ( $P 0.003$ ). Also at 1 year there was a significant difference in MTPM between the stable and unstable groups, mean 1.1 mm (SD 0.5) and 1.6 mm (SD 0.6), respectively ( $P 0.01$ ).

When analyzing inducible displacement as MTPM, the unstable group showed larger motions from rotatory forces than the stable group (Table 4). Considering inducible displacement and the direction of motions (SM), a tendency towards larger motions in the unstable group was found in most directions, but it reached significance only when an inwardly directed rotatory force was applied. Here the unstable group tilted into valgus ( $P 0.001$ ).

A correlation between migration as MTPM and inducible displacement as MTPM was found, weak in rotation,  $r 0.37$  ( $P 0.02$ ), but stronger in flexion,  $r 0.79$  ( $P < 0.001$ ). The correlation was also identified between a change in MTPM the second year and

Table 3. Inducible displacement (SM) in response to externally applied rotatory forces, as rotation of the tibial component around the sagittal axis, in the 3 prosthesis groups. Mean, SD

| Group              | Position |      |      |      |       |      |
|--------------------|----------|------|------|------|-------|------|
|                    | 1-3      |      | 1-4  |      | 3-4   |      |
| PCA (n 15)         | 0.03     | 0.26 | 0.05 | 0.33 | -0.06 | 0.33 |
| Tricon stem (n 15) | -0.19    | 0.25 | 0.10 | 0.36 | 0.25  | 0.39 |
| Tricon-M (n 13)    | -0.24    | 0.24 | 0.17 | 0.33 | 0.40  | 0.40 |
| <i>P</i>           | 0.02     |      | 0.9  |      | 0.03  |      |

1-3 The micromotion occurring between the supine and standing positions with an outwardly directed rotatory force of 10 Nm.

1-4 Same as 1-3 except for an inwardly directed force.

3-4 The micromotion between the positions from outwardly to inwardly directed forces.

Table 4. Inducible displacement as MTPM (magnitude in mm without direction) in the 2 groups with different prognosis, stable and unstable. Mean, SD

| Group           | Position <sup>a</sup> |      |      |      |      |      |
|-----------------|-----------------------|------|------|------|------|------|
|                 | 1-3                   |      | 1-4  |      | 3-4  |      |
| Stable (n 28)   | 0.36                  | 0.13 | 0.38 | 0.24 | 0.43 | 0.19 |
| Unstable (n 15) | 0.47                  | 0.19 | 0.49 | 0.27 | 0.61 | 0.03 |
| P               | 0.03                  |      | 0.2  |      | 0.03 |      |

<sup>a</sup> 1-3, 1-4 and 3-4, see Table 3.

inducible displacement as MTPM, in rotation,  $r$  0.42 ( $P$  0.008), and in flexion,  $r$  0.74 ( $P$  0.001).

No association was found between age, arthrosis stage, weight, HKA preoperatively, HKA postoperatively, prosthesis-tibia angles or clinical score (HSS) and the stability criteria (Table 1).

## Discussion

The previously established accuracy of RSA applied to knee arthroplasty, 0.2 mm for translational and 0.3° for rotatory movements (Ryd 1986), was accepted in this study because of the low average mean error, good marker configuration and small false movements in the reproducibility examination.

No detectable differences in migration, measured as MTPM, were found between the 3 groups, either in the level or in the pattern. SM in one direction, translation distally along the vertical axis, or subsidence, was increased in both Tricon groups. A reason for this may be that the flanged plastic pegs of the Tricon design resist full impaction at operation and only gradually permit the final settling. Another possible explanation, a stabilizing effect from the PCA fixation screw anteriorly, was considered less probable due to the poor purchase of this screw in cancellous bone only. As in all previous studies, migration of the tibial components was largest during the very early stage. This has been explained by the early remodeling of the interface, secondary to operative trauma. Part of this trauma has been attributed to the temperature effect and to unevenness in the cut surface (Toksvig-Larsen 1992), but the phenomenon is certainly multifactorial.

The MTPM levels of about 1.4 mm are in the intermediate range, compared to other cementless designs, whereas cemented tibial components migrate significantly less, mean 0.7 mm (Ryd et al. 1993, 1995). Previously, an 11 cm stem has been shown to reduce migration in the Freeman-Samuels-

son prosthesis (Albrektsson 1991), but this was not confirmed by Nilsson et al. (1989). In this study, the Tricon-M and the Tricon stem groups behaved similarly and the hypothesis of improved stability with a stem (here 8 cm) was not proven. In a 2-year follow-up RSA investigation, a comparison of these 2 models of Tricon prostheses was made, but only in rheumatoid arthritis patients, and the use of a stem brought no advantages in uncemented cases (Nilsson 1992). Experimental investigations have shown more stability with a stem than with posts, but only in resistance to off-set loadings, not in shear and torque (Walker et al. 1990). This is probably a design feature as a stem can only be evaluated in relation to one type of prosthesis and no extrapolations to other types are warranted. As to the Tricon-M design, 5-year RSA data are also available showing only slight continuous migration during 2-5 years, in uncemented cases from 1.4 mm to 1.6 mm MTPM (Nilsson and Kärrholm 1993).

The Tricon groups showed larger rotations than the PCA group in response to externally applied rotatory forces. This is probably due to the more conforming articular surface in Tricon than in the flat PCA plastic insert. This finding is in accordance with the assumption that conforming articular surfaces transmit higher forces to the prosthetic-bone interface (Werner et al. 1978, Thatcher et al. 1987). What bearing the conformity has on the concern for plastic wear was not investigated in this study. It is also possible that the softer polyethylene pegs of the Tricon design may be less efficient in resisting rotatory shear forces than the metal pegs of the PCA.

Considering the magnitude of motions (MTPM) induced by external stress, the unstable group showed larger displacement and there was a correlation between migration in the second year and inducible displacement. Thus, an association with migration has been established in this study. Such a relation seems logical and is compatible with the stress-accumulation scenario suggested by Huiskes (1993).

This has not been demonstrated before, possibly because the series were less homogeneous. The externally applied forces in the stress-series are designed to mimic everyday stresses and strains in the knee joint. Possibly, the magnitude of these forces and the ability to resist them determine the quality of the interface between prosthesis and bone. When the interface is exposed to cyclic motions, little bony ingrowth occurs (Pilliar et al. 1986, Burke et al. 1991, Toksvig-Larsen et al. 1991). The fact that the loosening process is initiated so early (Ryd et al. 1993) would make wear particles less important as a primary factor. In fact most knees revised for polyethylene breakdown have had soundly bonded tibial base-plates (Engl et al. 1992, Lindstrand et al. 1992). Instead, the results point to the importance of the early differentiation process at the interface, into fibrous tissue or fibrocartilage which, according to Giori et al. (1995), could be guided by mechanical factors.

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